ATTACHMENT 11

From: kmay@restorerobotics.com
To: Virani, Jitendra
Cc: An, Je Hi
Subject: RE: Restore Robotics -- Request for More Information
Date: Tuesday, July 21, 2020 1:08:46 PM
Attachments: image009.png
image010.png
image011.png
image012.png

CDR Virani,

(b) (4)

Regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

Restore Robotics
Replace. Repair. Restore.

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Monday, July 20, 2020 6:39 PM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update with your below email. We noticed that you have the following statement on your website: "da Vinci® and Intuitive® are registered trademarks of Intuitive Corporation. Restore Robotics is not affiliated with Intuitive®." Based on the information you provided with your below email, we do not think this statement is relevant on your website. Can you please update your website to remove this statement or provide your rationale on why it is needed?

Thanks.
Jit

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Friday, June 12, 2020 4:27 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

Thank you for your patience during these difficult times. (b) (4)
[redacted]

Regards,

Kevin

Kevin May
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www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Thursday, May 14, 2020 12:17 PM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update.

Jit

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Thursday, May 14, 2020 2:58 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

We are still focused on helping to provide PPE for the Covid-19 crisis.

(b) (4)

I will meet with the CEO and team to provide schedule for formal response in the coming week.

Kevin May
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kmay@restorerobotics.com

C 714-349-9015

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Thursday, May 14, 2020 11:06 AM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Hi Kevin,

Hope you are doing well and keeping it safe.

I wanted to touch base with you and see if you have an estimate on when might you be able to get back to us with your response to our questions?

Thanks.
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From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Friday, March 20, 2020 12:58 AM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

CDR Virani,

Our CEO and our entire staff is working only on two items right now: finding Ventilators for hospitals and PPE equipment for hospitals. This is something we cannot deviate from right now. Can we take a few weeks to get back to you? Because of this crisis we are not doing any other work.

My apologies for the delay.

Kevin May
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kmay@restorerobotics.com

C 714-349-9015

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Replace. Repair. Restore.

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Monday, March 16, 2020 6:22 AM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin for the update.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1611&S=F

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CDR Virani,
We have met with our regulatory consultants and are working on our response.
I need to get our CEO Clif Parker involved in our response. He has been extremely busy, as we are working on travel, work issues, taking care of our hospitals in this time of need and crafting company policy regarding the Covid-19 pandemic.
I will do my best to have a target date for you later this week.

Best Regards,

Kevin

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CDR Virani,

We are a very small company. We are meeting with our Regulatory consultant tomorrow. We will provide you a target date by this Friday.

Best Regards,

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www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

Restore Robotics
Replace. Repair. Restore.

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:31 AM
To: kmay@restorerobotics.com
Cc: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Thank you Kevin. Can you please provide an estimate on date by which you can provide us with the requested information?

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Jit

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
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CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Monday, March 9, 2020 3:06 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Dear CDR Virani,

We have received your email and we are working on our response to satisfy your inquiries .

Best regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Thursday, March 05, 2020 10:46 AM
To: kmay@restorerobotics.com
Subject: Restore Robotics -- Request for More Information

Dear Kevin,

My name is CDR Jitendra Virani and moving forward I will be your FDA contact person for the issues being discussed in the below email chain.

Thank you for your email response on February 27th, 2020 . As previously discussed, Restore Robotics believes the activities performed on hospital-owned equipment devices constitute repair. We would like to better understand the activities you perform as it is important to make sure the repair activities do not significantly change the performance or safety specifications, or intended use as described in 21 CFR 820.3(w). We are asking for the following information to confirm that your activities do not require a 510(k) or constitute other regulatory requirements.

1. What specific devices do you repair? Please provide the device trade names and original manufacturer names.

2. For each device, please describe the specific tasks that are conducted as a part of repairing/servicing?

3. Your website currently states, "Robotic Preventative Maintenance and Repair." Please describe what activities are performed as a part of preventative maintenance versus repair of the robotic devices?

4. Your website previously stated Restore Robotics extends the lives of these instruments beyond the OEM stated limit. We no longer see this statement on your website. Was it removed/edited because you no longer perform this activity? If you

continue to provide this service, please provide information on how many additional uses you extend the lives of the devices and how you confirm it remains safe and effective for its intended use (i.e. the performance and safety specifications are not significantly changed from the original performance and safety specifications).

5. Do you perform any verification or validation activity(ies) before, during, or after repairing/servicing a device? If so, please describe them. If not, please provide a rationale as to why they are not needed.

Thank you for continuing to work with us. We look forward to your responses and are happy to discuss any clarifications if needed.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1611&S=F

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Thursday, February 27, 2020 4:31 PM
To: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Follow up from FDA

Dr. An,

Thank you for your call and email. Restore Robotics is an independent service organization in the business of repairing hospital-owned medical devices. We do not sell any medical devices or take ownership of any medical devices sent to us for repairs. Restore Robotics only performs repairs of hospital-owned equipment. We do not perform cleaning or sterilization services of the medical devices. The repaired medical devices are returned non-sterile. Repaired devices must be cleaned

and sterilized by the hospital facility per the original manufacturer's instructions prior to use.

Restore Robotics receives a request from the hospital in the form of a purchase order or request for repair. We then repair the device per the hospital's request. The ownership of the device is always maintained by the hospital. The exact same device is returned after the repair to the hospital non-sterile. The hospital must process the device per manufacturer's instructions prior to use.

We believe that our services meet the definition of repair in the May 2018 FDA Report on the Quality, Safety, and effectiveness of Servicing of Medical Devices, in accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA). The device ownership is always maintained by the hospital. The repairs are done at the request of the hospital. No cleaning or sterilization is taking place. Therefore, we believe no 510(k) is needed for our operations.

In an abundance of caution, we have streamlined our website www.restorerobotics.com to reinforce the fact that we are solely in the business of providing repairs to hospitals seeking independent third-party service for their hospital-owned medical devices.

Let me know if you have any additional questions.

Regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

Restore Robotics
Replace. Repair. Restore.

From: An, Je Hi <Je.An@fda.hhs.gov>
Sent: Thursday, February 20, 2020 11:44 AM
To: kmay@restorerobotics.com
Subject: Follow up from FDA

Dear Mr. May,

We spoke on the phone today regarding Restore Robotics' activities and I wanted to follow up with you via email to summarize our conversation.

You state on your website www.restorerobotics.com that you restore robotic instruments and extend the lives of these instruments than the intended limit. Based on this information, we believe that a 510(k) is needed before you continue your operation.
You stated that you would provide within a week from today further description of your activities (for example, restoration of instruments) and an explanation of why a 510(k) is not needed.

Should you have any questions, please contact me.

Thank you,

Je Hi

Je Hi An, Ph.D.
Biomedical Engineer

Robotic Assisted Surgery Devices Team
DHT4A: Division of General Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

Tel: 240-402-0018
JeHi.An@fda.hhs.gov

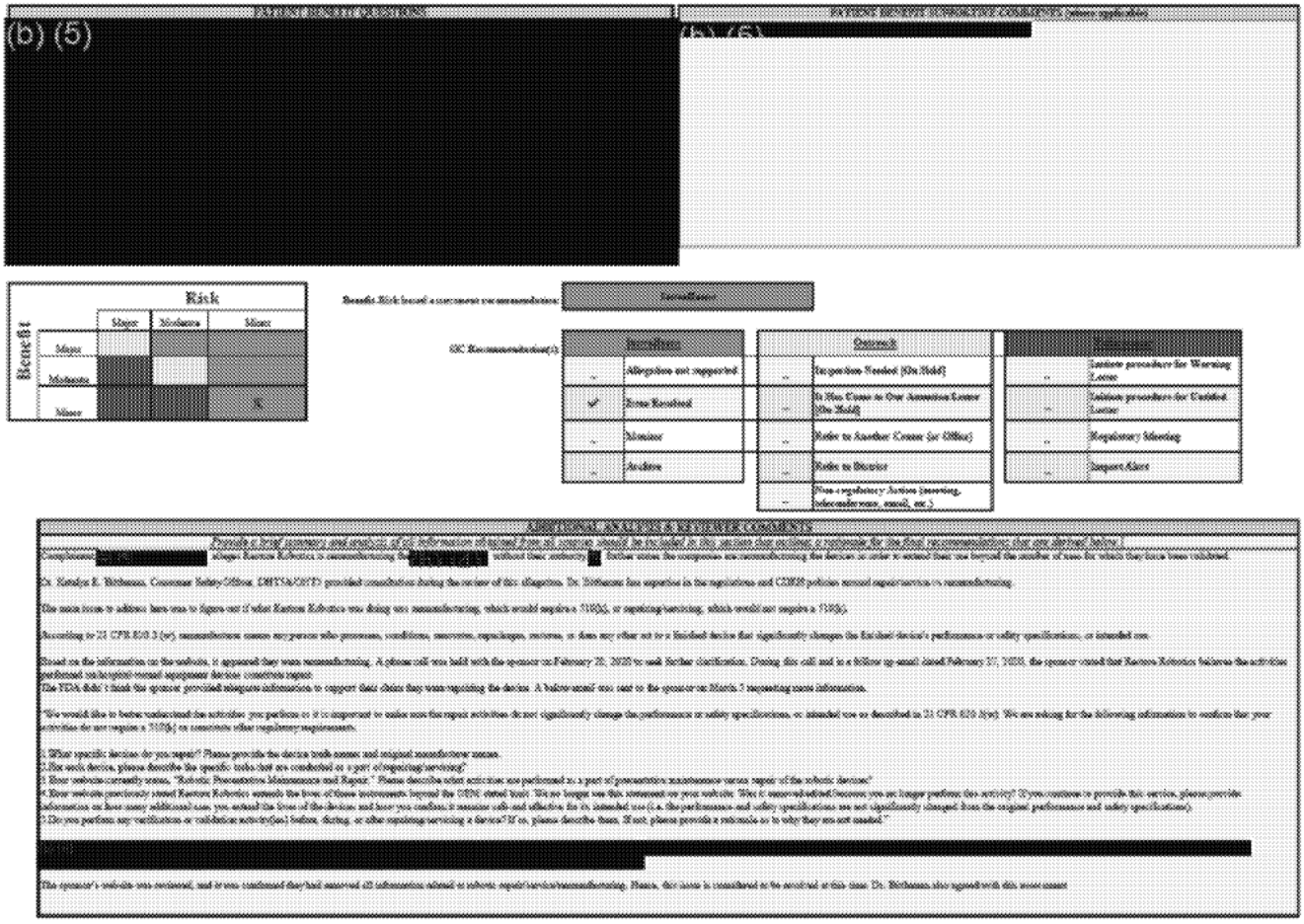
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: : CDRH Customer Satisfaction Survey

DPLC Allegation Assessment Review Memorandum

Digital Reviewer Signature: Jitendra V. Virani -S

Date	
Firm	Restore Robotics
Owner /Website Address	
FEI Number:	NA
Device Name:	Restore Robotics - EndoWrist Rapid reconditioning Program Manufacturer Initiative Surgical Inc (ISI)
Subject	Potential Remanufacturing 3rd party device without 510(k)
CTS Number(s):	CPT000153
CMS Number(s):	N/A

REGULATORY DETAILS	REGULATORY SUPPORTIVE COMMENTS (where applicable)
(b) (5)	
(b) (5)	(b) (5)
(b) (5)	

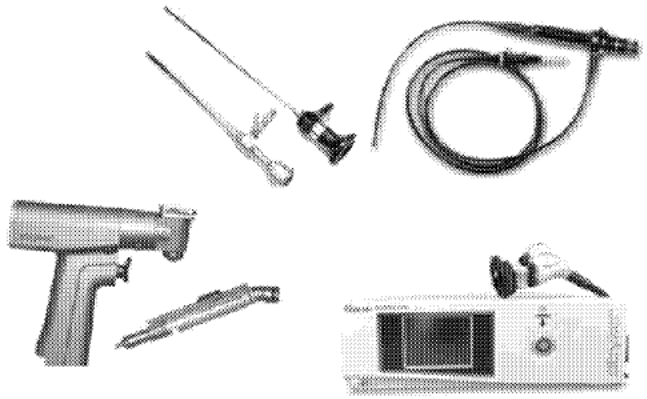


From: Bittleman, Katelyn
To: Virani, Jitendra
Cc: An, Je Hi; Chen, Long H; Silverstein, Joshua
Subject: RE: Restore Robotics -- Request for More Information
Date: Friday, July 10, 2020 9:56:21 PM
Attachments: image021.png
image022.png
image023.png
image004.png

Hi Jit,

I finally got to reviewing Restore Robotics response and their current website. Sorry for the delay. I don't see any references to robotic medical device repairs. (b) (5) [redacted]

Restore Robotics "Home" page:



Medical Device Repairs

- Ventilators
- Flexible Endoscopes
- Rigid Endoscopes
- Cameras, UltraSound Probes
- Fluid Waste Management Systems

Our advanced National Service Centers (each with a primary focus on one of the items listed above) have also provided contract manufacturing services to the top OEMs in their area of repair for over 25 years. Click here for more information.

Restore Robotics "Repairs" page:

WHY RESTORE

Save Money and Maintain High Quality

All work performed in an ISO 13485:2016 certified facility.

Stryker® Neptune® 2

Flexible Endoscopes

Rigid Endoscopes

TEE Probes

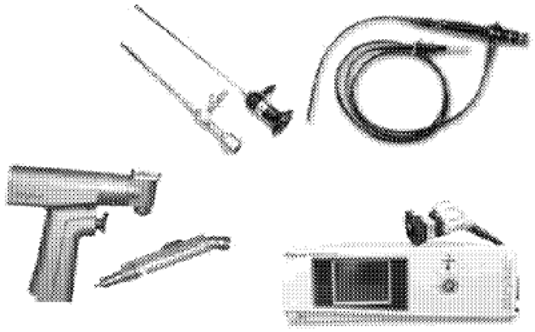
Ultrasound Probes

Neptune® 2 Rovers and Docking Stations

As of July 1, 2019 Stryker® will no longer be supporting repairs or Preventative Maintenance on the Stryker® Neptune® 2 Rovers and Neptune® 2 Docking Stations.

Reduce capital expenditures, lower long term costs and extend the life of your Neptune® 2 systems by at least 3 years.

Learn More



(b) (5)

-Katelyn

Katelyn R. Bittleman, Ph.D.
Consumer Safety Officer, Neurodiagnostic Devices Team

DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4250 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-1478
Katelyn.Bittleman@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have

received: https://www.research.net/s/cdrhcustomerservice?ID=1713&S=E

From: Virani, Jitendra
Sent: Friday, June 12, 2020 4:48 PM
To: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: An, Je Hi <Je.An@fda.hhs.gov>; Chen, Long H <Long.Chen@fda.hhs.gov>
Subject: RE: Restore Robotics -- Request for More Information

Hi Katelyn,

Please see most recent email from Restore Robotics informing us (b) (4) [redacted] However, their website still states, "Personal Protective Equipment & Robotic and Medical Device Repairs" and further state the following:

"Medical Device Repairs

- Ventilators
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Our advanced National Service Centers (each with a primary focus on one of the items listed above) have also provided contract manufacturing services to the top OEMs in their area of repair for over 25 years. Click here for more information."

Their website: https://www.restorerobotics.com/repairs

(b) (5) [redacted]

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Thank you for your patience during these difficult times. (b) (4) [redacted]

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CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. G456 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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Kevin May
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Team Lead

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Subject: RE: Restore Robotics -- Request for More Information

Dear CDR Virani,

We have received your email and we are working on our response to satisfy your inquiries .

Best regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

Restore Robotics
Replace. Repair. Restore.

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Thursday, March 05, 2020 10:46 AM
To: kmay@restorerobotics.com
Subject: Restore Robotics -- Request for More Information

Dear Kevin,

My name is CDR Jitendra Virani and moving forward I will be your FDA contact person for the issues being discussed in the below email chain.

Thank you for your email response on February 27th, 2020 . As previously discussed, Restore Robotics believes the activities performed on hospital-owned equipment devices constitute repair. We would like to better understand the activities you perform as it is important to make sure the repair activities do not significantly change the performance or safety specifications, or intended use as described in 21 CFR 820.3(w). We are asking for the following information to confirm that your activities do not require a 510(k) or constitute other regulatory requirements.

1. What specific devices do you repair? Please provide the device trade names and original manufacturer names.

2. For each device, please describe the specific tasks that are conducted as a part of repairing/servicing?

3. Your website currently states, "Robotic Preventative Maintenance and Repair." Please describe what activities are performed as a part of preventative maintenance versus repair of the robotic devices?

4. Your website previously stated Restore Robotics extends the lives of these instruments beyond the OEM stated limit. We no longer see this statement on your website. Was it removed/edited because you no longer perform this activity? If you continue to provide this service, please provide information on how many additional uses you extend the lives of the devices and how you confirm it remains safe and effective for its intended use (i.e. the performance and safety specifications are not significantly changed from the original performance and safety specifications).

5. Do you perform any verification or validation activity(ies) before, during, or after repairing/servicing a device? If so, please describe them. If not, please provide a rationale as to why they are not needed.

Thank you for continuing to work with us. We look forward to your responses and are happy to discuss any clarifications if needed.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

From: kmay@restorerobotics.com <kmay@restorerobotics.com>
Sent: Thursday, February 27, 2020 4:31 PM
To: An, Je Hi <Je.An@fda.hhs.gov>
Subject: RE: Follow up from FDA

Dr. An,

Thank you for your call and email. Restore Robotics is an independent service organization in the business of repairing hospital-owned medical devices. We do not sell any medical devices or take ownership of any medical devices sent to us for repairs. Restore Robotics only performs repairs of hospital-owned equipment. We do not perform cleaning or sterilization services of the medical devices. The repaired medical devices are returned non-sterile. Repaired devices must be cleaned and sterilized by the hospital facility per the original manufacturer's instructions prior to use.

Restore Robotics receives a request from the hospital in the form of a purchase order or request for repair. We then repair the device per the hospital's request. The ownership of the device is always maintained by the hospital. The exact same device is returned after the repair to the hospital non-sterile. The hospital must process the device per manufacturer's instructions prior to use.

We believe that our services meet the definition of repair in the May 2018 FDA Report on the Quality, Safety, and effectiveness of Servicing of Medical Devices, in accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA). The device ownership is always maintained by the hospital. The repairs are done at the request of the hospital. No cleaning or sterilization is taking place. Therefore, we believe no 510(k) is needed for our operations.

In an abundance of caution, we have streamlined our website www.restorerobotics.com to reinforce the fact that we are solely in the business of providing repairs to hospitals seeking independent third-party service for their hospital-owned medical devices.

Let me know if you have any additional questions.

Regards,

Kevin

Kevin May
Restore Robotics
www.restorerobotics.com
kmay@restorerobotics.com

C 714-349-9015

Restore Robotics
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From: An, Je Hi <Je.An@fda.hhs.gov>
Sent: Thursday, February 20, 2020 11:44 AM
To: kmay@restorerobotics.com
Subject: Follow up from FDA

Dear Mr. May,

We spoke on the phone today regarding Restore Robotics' activities and I wanted to follow up with you via email to summarize our conversation.

You state on your website www.restorerobotics.com that you restore robotic instruments and extend the lives of these instruments than the intended limit. Based on this information, we believe that a 510(k) is needed before you continue your operation.
You stated that you would provide within a week from today further description of your activities (for example, restoration of instruments) and an explanation of why a 510(k) is not needed.

Should you have any questions, please contact me.

Thank you,

Je Hi

Je Hi An, Ph.D.
Biomedical Engineer

Robotic Assisted Surgery Devices Team
DHT4A: Division of General Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

Tel: 240-402-0018
JeHi.An@fda.hhs.gov

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Am I allowed to use a Third Party for this service?

The recent US Supreme Court ruling regarding Lexmark provides the legal right to use a 3rd party for repairs. In a nutshell, if you paid for it no one can tell you wh you can use to repair it.

These are Limited-Use devices – is it within regulatory compliance to restore and re-use them?

The FDA recognizes only two types of use cases: single use and multiple use. These devices are classified as multiple use by the FDA.

Why does it still stop at 10 uses – Can't you extend that?

The 10-use protocol is part of the robot's software governing its "willingness" to allow the tool to be utilized. The robot's software is not something we can alter.

Will I get back the same tool that I sent in to be restored?

You will get back the tool that you submitted unless it fails during the testing phase.

How many times can a device be restored?

We have tested the instruments for 5 restore cycles without failure.

Do I need to ship in any special manner?

Common sense packaging is all that is needed and shipping by Ground is acceptable for these devices. For simplicity we recommend that while retrieving a new dev from inventory that you place the device to be restored in its box and ship once you have accumulated several devices – perhaps every 2-4 weeks depending on th volume of units to be restored.

New Paragraph

From: Virani, Jitendra
To: CDRH Device Allegations
Cc: Gomes, John; An, Je Hi; Barnett, Paola
Subject: Supp-doc-OHT4 Request - Unauthorized 3rd Remanufacturing/Repair of (b) (4)
Date: Friday, January 31, 2020 2:57:05 PM
Attachments: Cassandra.Young_013020_143157.pdf
(b) (4)

Dear Allegation Team:

OPEQ received the attached letter from (b) (4) . This letter informs FDA about 3rd parties remanufacturing (b) devices.

OHT4 reviews these devices and will work on this allegation. Can you please log this as allegation and send it forward to OHT4 soon? We would like to start working on this as soon as possible. (b) (5)

Thank You.
Jit

CDR Jitendra Virani
Acting Assistant Director

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

From: Virani, Jitendra
Sent: Friday, January 31, 2020 12:38 PM
To: CDRH-OPEQ-OHT4-DHT4A1-All <CDRH-OPEQ-OHT4-DHT4A1-All@fda.hhs.gov>; Carr, Jessica <Jessica.Carr@fda.hhs.gov>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Ardeshirpour, Yasaman <Yasaman.Ardeshirpour@fda.hhs.gov>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; Gomes, John <John.Gomes@fda.hhs.gov>

Cc: Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>
Subject: Unauthorized 3rd party repair of (b) (4)

RASD Team:

If you attended the RASD TPLC round presentation yesterday, you may recall Dr. Shuren commented on 3rd parties fixing up (b) (4) and selling back to hospitals. Please see attached document with more information on this topic. We will be working on this in coming days. I will discuss it with OHT4 on how to best address this. My initial thought is to have this get logged as an allegation.

Thanks.
Jit

From: Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
Sent: Thursday, January 30, 2020 6:49 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Cc: Stevenson, Jennifer R <Jennifer.Stevenson@fda.hhs.gov>; Korz, Dorian <Dorian.Korz@fda.hhs.gov>
Subject: Fwd: RASD

Jit
Please share with RASD team
Thank you
Binita

From: Young, Cassandra <Cassandra.Young@fda.hhs.gov>
Date: January 30, 2020 at 2:33:30 PM EST
To: Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
Subject: RASD

Attachment A

Restore Robotics
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Discussion of Risk Management and Liability With Regard to Surgical Robot Instrument Repair

Risk Management

Restore Robotics understood that any interaction with the robot would receive extra scrutiny so we achieved ISO 9001 certification for our repair facility and designed, built and consistently execute the repair process in a manner that has been validated to the highest international standards. These include the following:

1. Repair process flow created according to ISO:13485:2012
2. Repair processes validated according to ISO:13485:2012
3. Compliance with Risk Management and Analysis according to EN ISO 14971:2012 (meets ISO and FDA standards)
4. Compliance to Biocompatibility ISO 10993 Biological Evaluation of Medical Devices
5. Compliance to Medical Electrical Equipment standards IEC 60601
6. Verification reports to Simulated Life Testing according to ISO:13485:2012
7. Software validation according to ISO:13485:2012

Restore Robotics is unaware of any other repair facility that has performed such expensive and comprehensive testing of a repair process.

Furthermore, our service violates none of the standards that could necessitate a 510K. That is to say

- The hospital never loses ownership of the instrument
- We do not sterilize nor do we provide a sterile device after the repair
- There are no changes to the performance or safety specifications of the instrument.
- The devices intended use is not significantly altered
    - The EndoWrist's 510K and IFU denote the instrument as a reusable device and they remain so
    - By the FDA's definition, in order to violate the standard of "significantly altered" we would have to change the EndoWrist into a single use device.

Restore Robotics has more than 2 years of history with repairing EndoWrist instruments with well over 1500 repairs resulting in No adverse events and No communication issues between the repaired instrument and the Da Vinci system.

Liability

Other than the manner in which they are driven (human hand vs mechanics) these devices operate like any other endoscopic instrument hospitals have used for decades, thus Restore Robotics liability would be the same as any other 3rd party company a hospital currently utilizes to perform endoscopic instrument repairs.

Corp. Ofc. - 1275 Buford Hwy Ste 109 Suwanee Ga 30024
Repair Center - 4883 E. La Palma Ave, Suite 501B, Anaheim, CA 92807
WWW.RestoreRobotics.Com 678-518-0611

Restore Robotics
Replace. Repair. Restore.

From: Benesch, Bryan H.
To: CDRH Device Allegations
Subject: (b) (5)
Date: Friday, January 31, 2020 8:48:24 AM
Attachments: (b) (5)

Creator: Barbara

Name this sheet: HP- Cmpl-Orig- Restore Robotics - Rebotix Repair - EndoWrist Remanufacturers

Multiple: X Yes 2

Complaint Name: 1 of 2 Restore Robotics - (b) (4)
Remanufacturer

Date Received: 1/31/20

AIMs number: N/A

Supp-Doc Name(s): Supp-doc-Complainants Letter of Allegation,

URLs: https://www.restorerobotics.com/

Do **not** add to comments

Keyword: none
Add to CTS

Linkages to eRef: none found
Do not add to CTS

Address:
Add to CTS

Assign to:

Assigned by: Paula

(Notes: do not add to complaint) Please process as HP as requested by OHT4 attached.

Creator: Barbara

Name this sheet: Cmpl-Orig- Restore Robotics - Rebotix Repair - EndoWrist Remanufacturers

Multiple: X Yes No

Complaint Name: 2 of 2 Rebotix Repair - (b) (4)

Date Received: 1/31/20

AIMs number: N/A

Supp-Doc Name(s):	3 as named
URLs:	https://rebotixrepair.com/
Do **not** add to comments	
Keyword: Add to CTS	none
Linkages to eRef: Do not add to CTS	none found
Address: Add to CTS	
Assign to:	
Assigned by:	Paula

(Notes: do not add to complaint)

Please enter this as a trade complaint.

Thank you.

Bryan

Bryan H. Benesch
Senior Policy Advisor

Certified Quality Auditor
ASQ The Global Voice of Quality™

Regulation, Policy & Guidance Staff
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 1538 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-5506
Bryan.Benesch@fda.hhs.gov

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From: (b) (4)
Sent: Wednesday, January 29, 2020 11:45 PM
To: Maisel, William <William.Maisel@fda.hhs.gov>
Cc: Ashar, Binita S <Binita.Ashar@fda.hhs.gov>; Benesch, Bryan H. <Bryan.Benesch@fda.hhs.gov>
Subject: Letter to FDA re: remanufacturing of instruments

Dear Dr. Maisel,

Please find attached a copy of a letter that is also being sent by FedEx to you that addresses our safety concerns regarding remanufacturing activity on our instruments by third parties. Please let me know if you have any questions. I look forward to discussing this issue with you further at your convenience.
Warm Regards,
(b) (4)

(b) (4)

From: CDRH Device Allegations
To: (b) (4)
Subject: Allegations Sent to the FDA - BY - CPT2000125, CPT2000126
Date: Monday, February 10, 2020 10:50:00 AM
Attachments: image001.png

FDA U.S. FOOD & DRUG ADMINISTRATION

Document Number: CPT2000125,
CPT2000126

Dear (b) (4)

This is in response to your correspondence received into the CDRH Office of Regulatory Programs, Division of Regulatory Programs 3 (Market Intelligence), Allegation of Regulatory Misconduct Team on January 31, 2020.

Thank you for providing this information to the Food and Drug Administration (FDA). Information from regulated industry and/or complainants is very helpful to us in identifying problems with marketed products and possible violations of the laws that we enforce. We take such reports seriously, and we will evaluate this matter to determine what follow-up action is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem reported, the potential impact on the public health, and the availability of our resources.

While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed. Requests for this information can be submitted via the agency online FOIA submission address at http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm, or in writing to the following address:

Food and Drug Administration
Freedom of Information Staff
ELEM 1029
12420 Parklawn Drive
Rockville, Maryland 20857

If you have any questions regarding this letter, please contact the Allegations of Regulatory Misconduct Team email inbox at CDRHDeviceAllegations@fda.hhs.gov and reference the above document number.

Sincerely yours,

Allegation of Regulatory Misconduct Team
Division of Regulatory Programs 3 (Market Intelligence)
ORP | OPEQ | CDRH

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

Rebotix Repair LLC

539 Pasadena Ave S
Saint Petersburg, FL 33707-2125 | view map

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COMPANY OVERVIEW

REBOTIX REPAIR LLC in Saint Petersburg, FL.

COMPANY DETAILS

Location Type: Single Location

Ownership: Private

Year Founded: 2019

Have fresher information? Update

LATEST COMPANY NEWS

There is currently no press for this company.

READ ALL COMPANY NEWS IN THE COMPLETE COMPANY CREDIT REPORT

RECENT COMPANY ALERTS

Credit Risk Increase	No
Overall Payments	No
Peer Payments	No
Public Records	No
Financial News	No

ALERTS ON MORE THAN 5,000 COMPANIES TODAY, INCLUDING:

American Blue Ribbon Holdings LLC
Retech Systems LLC
Pinnacle West Capital Corp
Americas Christian Credit Union
North Valley Dermatology

Boeing Co
Perched
Southwest Power Pool Inc
Fastener Technology
Mcclellan Business Park LLC

COMMUNITY PAYMENT RATINGS

NO RATING

LATEST COMMUNITY REVIEWS OF THIS COMPANY

Cortera is much more than an awesome business directory! It's an active community where real business people share the real deal on real businesses.

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- Rate Rebotix Repair LLC on their payment behavior
- Ask your network about Rebotix Repair LLC with Cortera Circles

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Get more robust credit data solutions at a lower cost with Cortera's business solutions. Increase visibility into the big picture of your B2B customers. Our products were created to offer business professionals low-cost, high-value credit data solutions. Cortera products increase your understanding of your customers, prospects and suppliers, providing daily alerts and real-time updates. Give your company an edge by making better, more informed business decisions. SOFIE™ is the software engine that powers the data processing and analytics that are delivered in Cortera Pulse®, Reports, Scores, Boost®, and other products.

OTHER BUSINESSES NEARBY

American Leasing Electronics
Fortuno Investigations LLC
Sand Dollar Pools & Spas Inc
Microfirm
Dission Laundromat Inc
Cove CAY Storage LLC
Southern Home Healthcare Inc
Samos Corner
Fourward Designs LLC
Homera Technologies Inc

CONSULT REVIEW MEMORANDUM

DATE:	3/29/2020
TO:	Jitendra Virani, Team Lead Robotic Assisted Surgical Devices Team, DHT4A/OHT4/OPEQ/CDRH
FROM:	Katelyn Bittleman, Consumer Safety Officer Neurodiagnostic Devices Team, DHT5A/OHT5/OPEQ/CDRH
SUBJECT:	Allegation of Remanufactured Devices
FIRM:	Rebotix Repair
DEVICE(S):	(b) (4)
CTS TRACKING NUMBER:	CPT2000126 CON206059

CONSULT REQUEST:

(b) (4) has submitted an allegation of regulatory misconduct against Rebotix Repair for marketing remanufactured (b) (4) without proper clearance. Rebotix Repair believes their activities do not constitute remanufacturing and therefore do not require premarket notification. The consult request is to determine whether the activities performed by Rebotix Repair constitute remanufacturing and/or require a 510(k).

DEVICE SUMMARY:

(b) (4) refers to a catalog of surgical instruments including scissors, graspers, needle drivers, suction, and cautery instruments compatible with (b) (4). The instruments are reusable, however each instrument is marketed and programmed with a maximum number of surgical procedures based upon life testing.

(b) (4) has a number of 510(k)'s for (b) (4). The cleared Indications for Use for the most recent 510(k) (b) (4) states:

(b) (4)

(b) (4)

CONSULT EVALUATION:

(b) (5)

RECOMMENDATION:

Activities performed by Rebotix Repair on the (b) (4) to extend their life and function, significantly change the devices' intended use, constitute remanufacturing, and require premarket notification review to legally market.

Katelyn Bittleman -S
2020.03.29 13:52:23 -04'00'

(Reviewer eSignature)

From: Virani, Jitendra
To: Bittleman, Katelyn
Cc: Gupta, Jay
Subject: Consult Request CON206959 for CPT2000126 -- Rebotix Repair Repairing/Servicing vs Remanufacturing
Date: Thursday, March 19, 2020 1:44:42 PM
Attachments: image010.png

Hi Katelyn,

As you are aware OHT4 is working on two similar allegation from (b) (4) that two companies are remanufacturing their devices. We discussed one of these company (Restore Robotics) the other day over the phone. We discussed more information was needed from the company to determine if it is repair or remanufacturing. You helped me with drafting some questions to send out to this company to request more information.

The other company is Rebotix Repair. I sent them similar questions we sent to Restore Robotics. Robotix Repair has submitted their response. I have requested a separate subject consult from you to help review this response in below email.

Thank You.
Jit

From: Chris G <chris@rebotixrepair.com>
Sent: Thursday, March 19, 2020 1:13 PM
To: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: RE: Request for More Information on Rebotix Repair Repairing/Servicing Activities

Dear Jitendra,

Following are answers to your questions, submitted to us via email on 3-9-20. We feel strongly that the hospital service operations in which we are involved, are safe and effective, as well as conscientious with respect to public health economics.

You refer to 21 CFR 820.3(w) in your introduction. We assume you are referring to the clause that defines the term "remanufacturer". If so, we are confused by this reference since we have only ever seen 21CFR820 applied to a remanufacturer that reprocesses and sells medical devices, as is the case with single use devices which involve sterilization and repackaging. For multiple use devices, many operations such as sharpening and repair, are frequently done by hospitals and third parties. We have never heard of 21CFR820 QSR (which includes design controls) being applied to repair processes performed on multiple use devices or other hospital owned equipment. However, we do believe a formal quality system should be used for all such maintenance.

From the 21 CFR 820.1 Applicability: *"(2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico."* In 820.1(a) we also read that: *"This regulation does not apply to manufacturers of*

components or parts of finished devices".

Since we supply a service replacement component, and do not manufacture a finished product, we believe this regulation does not apply to us.

Our company did attend the FDA "Public Workshop - Medical Device Servicing and Remanufacturing Activities" (facilitated by Joshua Silverstein) where new potential guidance for service operations was discussed, and feel confident that the service process being discussed here is very consistent with the new ideas being presented for "permissible repairs". However, we (and the hospitals) are trying to understand why this repair is being chosen as a candidate for applying these new regulatory concepts when we have no information of any further activity with the guidance, or any new regulation. If you could help us to understand that we would appreciate it.

Specific to your questions:

1. *What specific devices do you repair? Please provide the device trade names and original manufacturer names.*

(b) (4)

2. *For each device, please describe the specific tasks that are conducting as a part of repairing/servicing?*

(b) (4)

3. *Are you providing service that may extend the lives of devices beyond the original equipment manufacturer (OEM) stated limit. If yes, please provide information on how many additional uses you extend the lives of the devices and how you confirm it remains safe and effective for its intended use (i.e. the performance and safety specifications are not significantly changed from the original performance and safety specifications).*

Yes, hospitals do use this service to operate the instrument beyond the manufacturer's original recommendation, and as we are sure you are aware, this is not at all unusual.

We are confident applying these standard, endoscopic instrument repair processes to the (b) (4), since this is supported by the language below from the 510(k)

approval for the (b) (4):

These standard and identical surgical tools have been serviced/sharpened/repaired for many years by hospitals all across the USA, and it is true that this often results in a longer life than the manufacturer recommends for a new purchase.

As these devices are multiple-use devices, intended to be cleaned and sterilized by the hospital, the repair process ensures the internal components continue to facilitate proper reprocessing as intended by the OEM. The reprocessing steps for the devices are never altered or intended to be altered.

We do not control uses at the hospital. We simply facilitate the repair/sharpening of their instrument. The hospital decides for each individual instrument based on their evaluation. In fact, it is very common for instruments to be taken out of service prior to reaching the manufacturer's original recommendation because they are not considered sufficiently sharp to continue use. From our broad experience and understanding, hospitals have always had the responsibility to manage the safety of instruments that they own, including making these kinds of maintenance decisions.

Regarding safety and effectiveness, we believe this repair is quite low on the risk spectrum for medical device service operations, but have performed formal risk management for the

aspect of the repair which is related to our component (well beyond state-of-the art for repair processes). The replacement component allows for the resetting of the usage counter ONLY. It is important to note that the small memory device involved is not accessed during the surgical procedure. This information is only accessed during installation onto the host system and prior to the surgeon taking control of the device.

Any instrument being repaired must pass all functional and safety specifications for that devices specific use. For example, a bipolar forcep must pass all standard grasping efficiency tests for a forcep of that size, along with all electrocautery safety and performance testing for that devices rated voltage. A monopolar scissor would have to pass all cutting efficiency tests as well as electrocautery safety and performance testing for its rated voltage.

4. Do you perform any verification or validation activity(ies) before, during, or after repairing/servicing a device? If so, please describe them. If not, please provide a rationale as to why they are not needed.

(b) (4)

These records, including formal test and inspection data, are always documented and retained for each repair done by us for the hospital. Our belief is that hospitals maintain an equivalent record when they perform the repairs.

We would be glad to make ourselves available for a follow-up phone call to discuss this and

any other questions you may have about our repair. Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix™
your prescription for savings
539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (b) (6)
www.rebotixrepair.com

From: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Sent: Monday, March 9, 2020 2:17 PM
To: Chris G <chris@rebotixrepair.com>
Subject: Request for More Information on Rebotix Repair Repairing/Servicing Activities

Dear Chris,

My name is CDR Jitendra Virani and moving forward I will be your FDA contact person for the issues being discussed in the below email chain.

Thank you for your email response dated March 6, 2020. We would like to better understand the activities Rebotix Repair performs as it is important to make sure the repair activities do not significantly change the performance or safety specifications, or intended use as described in 21 CFR 820.3(w). We are asking for more information listed below to confirm that your activities do not require a 510(k) or constitute other regulatory requirements.

1. What specific devices do you repair? Please provide the device trade names and original manufacturer names.

2. For each device, please describe the specific tasks that are conducting as a part of repairing/servicing?

3. Are you providing service that may extend the lives of devices beyond the original equipment manufacturer (OEM) stated limit. If yes, please provide information on how many additional uses you extend the lives of the devices and how you confirm it remains safe and effective for its intended use (i.e. the performance and safety

specifications are not significantly changed from the original performance and safety specifications).

4. Do you perform any verification or validation activity(ies) before, during, or after repairing/servicing a device? If so, please describe them. If not, please provide a rationale as to why they are not needed.

Thank you for continuing to work with us. We look forward to your responses and are happy to discuss any clarifications if needed.

Sincerely,

CDR Jitendra Virani
Team Lead

Robotic Assisted Surgical Devices Team
DHT4A: Division of General Surgical Devices | OHT4: Office of Surgical and Infection Control Devices | Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G456 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6398
jitendra.virani@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Chris G <chris@rebotixrepair.com>
Sent: Friday, March 6, 2020 11:59 AM
To: An, Je Hi <Je.An@fda.hhs.gov>; Greg Fiegel <GregFiegel@rebotixrepair.com>
Cc: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: RE: Follow up from FDA

Dear Je Hi,

We are happy to provide a clearer description of our current activities in the marketplace. Following your email, we have reviewed and updated our website to better portray our current activities. The phrase "authorized service centers" is currently irrelevant, as there are no longer any third-party service centers in the USA (we have removed this language from our website). The majority of the servicing entities have been hospital service departments, in which repairs are done internal to the

hospital system.

Rebotix Repair carries out two activities in the marketplace:

- Providing a repair component to hospitals to service their instruments, along with instructions and support
- Repair of hospital-owned instruments as a direct service provider to the healthcare institution

There is never any sale or resale of surgical instruments or any other medical device associated with our repair service. There is also never change of ownership. When instruments are repaired outside of the hospital itself, they are carefully tracked by serial number and returned to their original owners. Upon return, they pass through normal processes for similar incoming instruments that temporarily leave the hospital for sharpening, etc.

It is our belief that the original manufacturer, attempting to force a new instrument purchase, is no different than other similar manufacturers encouraging a purchase of new equipment over a repair. Hospitals commonly make safety and efficacy decisions about service operations on medical equipment they own, and we believe our repair service is no different.

We hope that this clarifies our activities and explains our position on why our repair services do not require a 510(k).

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix
your prescription for savings
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St. Petersburg, FL 33707
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From: An, Je Hi <Je.An@fda.hhs.gov>
Sent: Friday, February 28, 2020 9:19 AM

To: Chris G <chris@rebotixrepair.com>; Greg Fiegel <GregFiegel@rebotixrepair.com>
Cc: Virani, Jitendra <Jitendra.Virani@fda.hhs.gov>
Subject: Follow up from FDA

Dear Chris,

This is a follow up our phone conversation with you on February 28, 2020. I also spoke on the phone on February 20, 2020 with Mr. Greg Fiegel and Mr. Joe Morrison regarding your company's activities and I wanted to follow up with you via email to summarize our conversation.

Your company states on your website www.rebotixrepair.com that your technology allows your authorized service centers to inspect and recondition instruments when the original manufacturers attempts to force a new purchase. Based on this information, we believe that a 510(k) is needed before you continue your operation.

You stated that you would provide further description of your activities (for example, inspection and recondition of instruments) and an explanation of why a 510(k) is not needed by March 6, 2020. Please confirm the receipt of this email.

Should you have any questions, please contact me.

Thank you,

Je Hi

Je Hi An, Ph.D.
Biomedical Engineer

Robotic Assisted Surgery Devices Team
DHT4A: Division of General Surgery Devices | OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

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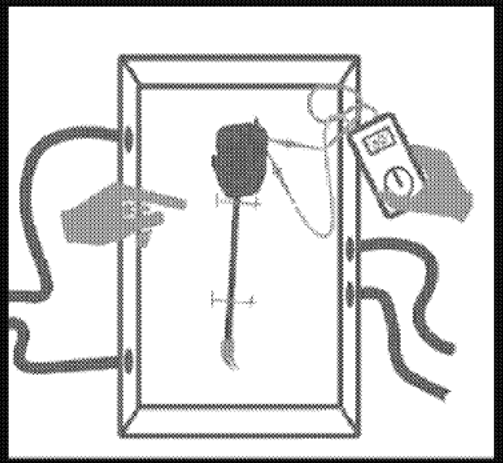
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: : CDRH Customer Satisfaction Survey

About Us



Robotic Surgery Made More Practical

Surgery has come a long way just within our lifetimes. Robotic technology has made minimally invasive surgery more convenient and efficient. But to many across the world, there are significant issues with economic practicality and ecological responsibility.
That is where we come in to lend a hand.

What Rebotix Repair Provides

We provide a specialized service process that puts hospitals back in control of their robotic surgical instruments, as for similar surgical instruments. Our technology allows our authorized service centers to inspect and recondition instruments when the original manufacturer attempts to force a new purchase (that the hospital may consider unnecessary).